UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

SABRINA MATTHEWS, Plaintiff,	§ § §	
v.	§	CIVIL ACTION NO. 1:11-CV-01077-SS
AMERICAN MEDICAL SYSTEMS, INC., Defendant.	§ § §	

PLAINTIFF SABRINA MATTHEWS' FIRST AMENDED COMPLAINT

TO THE HONORABLE UNITED STATES DISTRICT COURT:

COMES NOW Plaintiff Sabrina Matthews, by counsel, Daniel R. Thering, and for her First Amended Complaint against American Medical Systems, Inc. ("AMS"), alleges as follows:

PARTIES

1. Plaintiff is a natural person and is a citizen of the State of Texas.

2. Defendant AMS is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in the State of Minnesota.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this matter based upon 28 U.S.C. § 1332(a) because the Plaintiff and the Defendant are citizens of different states and the amount in controversy exceeds $75,000.00 excluding interest and costs.

4. AMS is subject to personal jurisdiction in the U.S. District Court for the Western District of Texas because AMS systematically and continually conducts business in this District and throughout the United States.

FACTS

5. AMS designs, manufactures, markets, packages, labels and sells medical devices, including the Monarc Subfascial Hammock and mesh (hereinafter the "Product"). The Product

is a medical device implanted in certain women like Plaintiff to treat pelvic organ prolapse and stress urinary incontinence.

6. AMS designed, manufactured, marketed, packaged, labeled, sold and placed in the stream of commerce the Product which was implanted in Plaintiff in 2006. Due to the defective design, defective manufacturing, defective marketing, and negligence by AMS, the Product has caused Plaintiff severe and permanent bodily injuries and significant mental and physical pain and suffering.

7. Plaintiff did not experience pain and did not have knowledge of the erosion of the Product which caused her injuries until she received her diagnosis and underwent the first of three surgeries to remove the Product in 2008. Plaintiff is still undergoing treatment to remove the remainder of the Product from its implanted position in Plaintiff's body. The nature of Plaintiff's injuries caused by the Product was inherently undiscoverable because her injury resulted from an implanted device. Further, the injury itself was objectively verifiable because the erosion of the Product was the cause of the injuries Plaintiff sustained.

8. The Product failed to correct or minimize Plaintiff's condition which was the purpose of implantation of the Product. Plaintiff continues to suffer from stress urinary incontinence at a worse rate than prior to implantation of the Product.

9. The Product has numerous defects that create an unreasonably high risk of dangerous injuries and side effects with severe permanent adverse health consequences. These defects include, but are not limited to the following:

a. The Product is made of material that is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health;

b. The Product's mesh material harbors infections that adversely affect human tissues and patient health;

c. The Product's mesh migrate from the location of their implantation, adversely affecting tissues and patient health;

d. The Product's mesh material abrades tissues adversely affecting patient health;

e. The Product's mesh regularly fails to perform the purpose of its implantation such that the patient requires removal of the device and repeated treatment and surgeries;

f. Due to the various defects, the Product's mesh regularly causes significant injury to patients such that the Product must be removed, resulting in additional surgery;

g. The Product's mesh becomes embedded in human tissue over time such that removal is often required, which process causes damage to organs and tissues, adversely affecting patient health; and,

h. The Product is defective in shape composition, weight, physical chemical and mechanical properties and is inappropriately engineered for use in the female pelvis.

10. The Product creates an unreasonable risk of injury and other adverse health consequences for the patient, such as vaginal erosion, infection, extrusion, perforation, chronic pain and abscess.

11. AMS was aware of the numerous defects and unreasonable risks of the Product outlined above prior to implantation of the Product in Plaintiff. Despite the knowledge AMS had of the defects and unreasonable risks of the Product, AMS manufactured, marketed and distributed the

Product with the intent that it would be implanted in patients like Plaintiff. AMS was aware that implanting the Product in patients was likely to cause them injury and harm.

12. Alternatively, AMS failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Product into patients.

13. AMS made public statements asserting that implanting the Product in patients was safe and would not cause harm to patients. AMS made these public statements in the form of written product descriptions, product labels, promotional materials and other materials. AMS made the statements intending that medical professionals and members of the public would rely upon them, and intending that the Product would be purchased by and implanted into members of the public. When AMS made the statements, AMS knew or should have known the statements were false.

14. Representatives of AMS made statements to medical professionals and other individuals that implanting the Product in patients was safe and would not cause harm to patients. When AMS representatives made these statements, they knew or should have known they were false.

15. AMS knowingly and deliberately made material misrepresentations to the federal Food and Drug Administration concerning the design, manufacture, safety, and efficacy of the Product.

16. AMS knew or should have known the Product caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and abscesses in women implanted with the Product because AMS was on notice of these numerous bodily injuries caused by the Product.

17. AMS continued to market the Product and sold thousands of Products in the United States, even though AMS knew or should have known the Product created a foreseeable, unreasonable risk of harm to members of the public.

18. AMS never provided physicians who implanted the Product or women implanted with the Product with adequate warning or information of the risks that the Product causes an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and/or abscesses.

COUNT 1- BREACH OF WARRANTY

19. Plaintiff incorporates the foregoing paragraphs as though the same were set forth at length herein.

20. The Product implanted in Plaintiff failed to function as intended and as represented by AMS because rather than relieving the symptoms or otherwise alleviating the medical problems that it was intended to cure, the Product actually caused Plaintiff to suffer infection or inflammation, tissue abrasion, and other severe adverse health consequences. Thus, the Product was not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations or representations of AMS.

21. AMS knew the Product was to be used for the particular purpose for which it was used on Plaintiff. Further, AMS knew its expertise was relied upon to furnish suitable goods.

22. AMS breached express warranties, the implied warranty of merchantability, and the warranty of fitness for a particular purpose because the Product failed to conform to AMS's representations and was not suitable for the purpose for which it was used.

23. Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and incurred economic loss because of AMS's breach of warranty.

COUNT 2- FRAUD

24. Plaintiff incorporates the foregoing paragraphs as though the same were set forth at length herein.

25. AMS, who had reason to know that its representations would reach a class of which Plaintiff was a member, made public statements asserting that implanting the Product in patients was safe and would not cause harm to patients. AMS made these public statements in the form of written product descriptions, product labels, promotional materials and other materials.

26. These statements were material because they were the basis of Plaintiff's physician's recommendation and Plaintiff's decision to have the Product implanted. In fact, Plaintiff relied on the false representation and had the Product implanted.

27. AMS made the statements intending that medical professionals and members of the public would rely upon them, and intending that the Product would be purchased by and implanted into members of the public.

28. When AMS made the statements, AMS knew or should have known the statements were false. AMS was on notice of numerous bodily injuries caused by the Product; thus, AMS knew or should have known the Product was not safe and that it caused an unreasonably high rate of vaginal erosion, infection, extrusion, perforation, chronic pain and abscesses in women implanted with the Product.

29. Plaintiff's reliance on AMS's false representations directly and proximately caused injury to Plaintiff which resulted in the damages set out in the Damages section below.

DAMAGES

30. As a direct and proximate result of Defendant's conduct, Plaintiff suffered the following injuries and damages:

(a) Medical expenses in the past and future;

(b) Physical pain and mental anguish in the past and future;

(c) Disfigurement in the past and future.

31. Punitive damages. At the time AMS designed, manufactured, marketed, labeled, packaged and sold the dangerous and defective Product and failed to adequately warn Plaintiff of the dangerous and defective nature of the Product, AMS knew, or in the exercise of the appropriate degree of care should have known, that its conduct created a high degree of probability of injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiff, and such conduct warrants the imposition of punitive damages.

PRAYER

WHEREFORE, Plaintiff Sabrina Matthews demands trial by jury, and that judgment be entered in Plaintiff's favor against AMS for compensatory and punitive damages, as well as costs, attorney fees, interest, and any other relief, monetary or equitable, to which Plaintiff is justly entitled.

Dated: December 30, 2011.

Respectfully Submitted,

THERING MCCARLEY, PLLC

/s/ Daniel R. Thering
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SABRINA MATTHEWS

CERTIFICATE OF SERVICE

I certify that on December 30, 2011 a true and correct copy of Plaintiff's First Amended Complaint was electronically filed on the CM/ECF system, which will automatically serve a Notice of Electronic Filing on the attorneys in charge for Defendant listed below.

/s/ Daniel R. Thering
DANIEL R. THERING

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